9110-04-P

#### DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2013-0499]

Change-1 to Navigation and Inspection Circular 04-08

AGENCY: Coast Guard, DHS.

**ACTION:** Notice of availability.

SUMMARY: The Coast Guard announces the availability of Change-1 to Navigation and Vessel Inspection Circular 04-08, "Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials" (NVIC 04-08). Change-1 to NVIC 04-08 contains a summary and clarification of Coast Guard policies regarding the criteria for granting medical waivers to merchant mariner credential applicants who have had either anti-tachycardia devices or implantable cardioverter defibrillators implanted, and to applicants who have had a seizure. This notice also addresses comments we received in response to Coast Guard notices published in the Federal Register on September 7, 2012, and March 25, 2013 soliciting public comments on these issues. DATES: Change-1 to NVIC 04-08 is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: NVIC 04-08 is available in the docket and can be viewed by going to http://www.regulations.gov and using

"USCG-2013-0499" as your search term. Locate this notice in the search results. NVIC 04-08 is available by clicking the "Supporting Documents" link. NVIC 04-08 is also available on the Coast Guard's website at:

www.uscg.mil/nmc.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or e-mail Lieutenant Ashley Holm, Office of Commercial Vessel Compliance (CG-CVC), 202-372-1128, e-mail MMCPolicy@uscg.mil. If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

#### SUPPLEMENTARY INFORMATION:

#### I. Background and Purpose

## General Waiver Criteria

Coast Guard regulations in 46 CFR 10.215 contain the medical standards that merchant mariner applicants must meet prior to being issued a merchant mariner credential (MMC). In cases where the applicant does not meet the medical standards in 46 CFR 10.215, the Coast Guard may issue a waiver when extenuating circumstances exist that warrant special consideration (see 46 CFR 10.215(g)).

Anti-tachycardia Devices and Implantable Cardioverter
Defibrillators

Coast Guard guidance in NVIC 04-08 provides that antitachycardia devices and implantable cardioverter defibrillators (ICDs) are generally not waiverable. Prior to issuing Change-1 to NVIC 04-08, Coast Guard guidance did not identify waiver criteria associated with antitachycardia devices or ICDs, rendering it difficult for Coast Guard personnel to consistently evaluate merchant mariner applicants with anti-tachycardia devices or ICDs, and assess whether an applicant's medical condition warranted granting a medical waiver under 46 CFR 10.215(g). Enclosure (7) to NVIC 04-08 now provides guidelines to use when assessing an applicant's eligibility for a waiver.

On September 7, 2012 we published a notice in the <u>Federal Register</u> requesting public comments on this issue (77 FR 55174). On December 17, 2012, we re-opened and extended the public comment period for an additional 30 days to provide additional opportunity to comment (77 FR 74630). We summarize the policy in Enclosure (7) to NVIC 04-08 and address the public comments below.

# Seizures

Coast Guard regulations in 46 CFR 10.215(d) state that a convulsive disorder (i.e., seizure disorder) could lead to an applicant's disqualification from receiving a credential. Prior to issuing Change-1 to NVIC 04-08, Coast

Guard guidance did not identify waiver criteria associated with applicants that had a history of seizures rendering it difficult for Coast Guard personnel to consistently evaluate merchant mariner applicants with seizures and assess whether an applicant's medical condition warranted granting a medical waiver under 46 CFR 10.215(g).

Enclosure (8) to NVIC 04-08 now provides guidelines to use when assessing an applicant's eligibility for a waiver.

On March 25, 2013 we published a notice in the <u>Federal</u>

<u>Register</u> requesting public comments on this issue (78 FR

17917). We summarize the policies in Enclosure (8) to NVIC

04-08 and address the public comments below.

## II. Discussion

# ICD Policy

Prior to Change-1, NVIC 04-08 referred applicants to the Coast Guard's National Maritime Center (NMC) for guidance on the treatment of ICDs. ICDs were generally not waiverable. Enclosure (7) provides a list of criteria to be considered when evaluating an application from a mariner with an ICD. While the policy remains that ICDs are generally not waiverable, the criteria in Enclosure (7) will identify those limited situations where a waiver will be considered. The criteria that must be met to be considered for a waiver are:

- (1) The applicant does not have a diagnosis of a cardiac channelopathy affecting the electrical conduction of the heart (to include Brugada syndrome, Long QT syndrome, etc.);
- (2) The applicant does not have a prior history of ventricular fibrillation or episodes of sustained ventricular tachycardia within the last three years;
- (3) The ICD or anti-tachycardia device was implanted more than three years ago;
- (4) The ICD has not fired nor has the applicant required anti-tachycardia pacing therapy within the last three years;
- (5) There are no additional risk factors for inappropriate shock such as uncontrolled atrial fibrillation:
- (6) The applicant's left ventricular ejection fraction (EF)<sup>1</sup> is greater than 35% with a steady or improving trend;
- (7) There is no history of any symptomatic or clinically significant heart failure in the past two years;

5

<sup>&</sup>lt;sup>1</sup> The left ventricular ejection fraction measures the percentage of blood that the left ventricle of the heart is able to pump with each beat. A normal ejection fraction is greater than 50%.

- (8) There is no evidence of significant reversible ischemia on myocardial perfusion imaging exercise stress testing;
- (9) The applicant's exercise capacity on formal stress testing (using standard Bruce Protocol)<sup>2</sup> is greater than or equal to 8 metabolic equivalents (METs);<sup>3</sup>
- (10) The applicant's treating cardiologist or electrophysiologist provides a written assessment of the individual that supports a determination that the mariner is at low risk for future arrhythmia, adverse cardiac event or sudden incapacitation based upon objective testing and standard evaluation tools; and
- (11) The applicant does not have any other medical conditions which may alone, or in combination with an ICD or anti-tachycardia device, pose an unacceptable risk for sudden incapacitation.

## Discussion of Public Comments on ICD Policy

On September 7, 2012 we published a notice in the Federal Register requesting public comments on proposed ICD

The Bruce protocol is a diagnostic test used in the evaluation of cardiac function, developed by Robert A. Bruce. It is a treadmill exercise test with set stages to ensure standardized results. Each stage has a pre-set incline and speed. A stage is 3 minutes long.

METs are a measure of physical work or exercise capacity. While there is no direct correlation, generally the physical ability guidelines in Enclosure (2) to NVIC 04-08 are similar to 6 METs. 8 METs are called for in the NVIC because the higher threshold results in better diagnostic and prognostic information. A mariner facing an emergency situation could likely be expected to have to function at least at 8 METs.

policy (77 FR 55174). We received approximately 37 comments on whether to grant waivers for anti-tachycardia devices or ICDs and the proposed criteria for such waivers. The majority of the comments were supportive of the proposed policy.

Many commenters referenced specific individuals that they argued were well qualified to hold a merchant mariner credential, despite having an ICD. Although this notice was not designed to render fitness determinations for specific individuals, the Coast Guard acknowledges that there may be some mariners with ICDs who warrant consideration for a medical waiver. The new policy clarification seeks to identify those limited situations where a waiver will be considered.

Several commenters felt that a requirement for applicants to reach 10 metabolic equivalents (METs) on a stress test using the standard Bruce Protocol was excessive. Instead, these commenters favored a standard of 8 METs, similar to the standard for other cardiac conditions addressed in NVIC 04-08. The Coast Guard proposed use of the 10 METs standard because it provides additional prognostic information over the 8 MET standard. Following review of the public comments, however, the Coast Guard considered that, when combined with the stringency of

all of the criteria required by the policy, the 8 METs standard provides sufficient prognostic information for evaluation. The Coast Guard, therefore, agrees with these commenters, and Change-1 incorporates 8 METs as the relevant standard.

Many commenters agreed with establishing waiver criteria, but they suggested that some of the proposed criteria were too restrictive (3 year exclusionary period, 10 METs, EF >40%, etc.). Several commenters expressed concern that the proposed checklist format was somewhat rigid, and that it over-simplified the process to a "go/nogo" decision that would not allow all factors to be considered. In response to these comments, we have determined that a relatively stringent set of criteria with respect to anti-tachycardia devices and ICDs is necessary because an underlying medical condition that warrants treatment with an ICD generally poses an unacceptable risk for sudden incapacitation. We developed the guidelines in Enclosure (7) to NVIC 04-08 for evaluating whether the underlying condition has improved significantly, and to help determine whether it no longer poses an inordinate risk. This allows for a margin of safety for individuals with ICDs who are seeking to work in a safety-sensitive position. The policy allows for an individual assessment,

and, under exceptional circumstances, applicants who do not meet all of the criteria may be eligible for a waiver if they can demonstrate to the satisfaction of the Coast Guard that there is not an inordinate risk. We will continue to assess whether this policy strikes the proper balance between public safety and an individual's interest in holding a merchant mariner credential.

Many commenters favored a case-by-case or individualized assessment of the applicant's condition; as opposed to a blanket denial for all applicants with ICDs. We note that even prior to Change-1, NVIC 04-08 has included a case-by-case evaluation of the applicant's condition. We developed the criteria in Enclosure (7) to NVIC 04-08 in order to provide a framework for those evaluations.

Some commenters favored offering credential limitations, instead of denial, if the condition still posed some risk. We note that applicants who do not meet all of the outlined criteria in Enclosure (7) to NVIC 04-08 may be considered for a waiver if the Coast Guard is satisfied that the risk can be reduced to an acceptable level. This may require limiting the scope of the applicant's credential to enforce certain working conditions that may reduce the risk of sudden

incapacitation. When circumstances warrant, the Coast Guard will work with individual applicants to tailor restrictions and limitations appropriate to individual situations.

Many commenters felt that a cardiologist's assessment should be sufficient for determining whether the applicant's medical condition is safe enough to warrant granting a waiver. The Coast Guard disagrees. The Coast Guard wishes to emphasize that mariner credentials often enable individuals to work in safety-sensitive positions aboard vessels, which amplifies the risks and potential consequences of a condition requiring use of an ICD or anti-tachycardia device. Accordingly, the Coast Guard has determined that a mariner's self-evaluation, or even the evaluation of a physician, is not sufficient evidence that the ICD, anti-tachycardia device, or underlying condition pose no inordinate risk. While the Coast Guard gives the treating physician's evaluation great weight, it is not the sole factor to consider. Because the mariner's safety and public safety are at stake, the Coast Guard has determined it must also consider the objective criteria outlined in Enclosure 7 to NVIC 04-08 in making the final decision of whether to grant a mariner's credential.

Many commenters pointed out the risks to maritime safety posed by prohibiting service as a mariner solely on the basis of the mode of treatment (e.g., ICDs). These commenters felt that such a prohibition would lead mariners to choose to forego medical treatment out of fear of losing their jobs. This would pose a significant risk to both the mariner and the public. Several commenters stated that a mariner with a known, closely-managed medical condition and an ICD, is far safer for the public and maritime industry than a mariner not seeking care, with undiagnosed medical conditions. The Coast Guard shares these concerns, and we crafted Enclosure (7) to NVIC 04-08 to focus more on the underlying condition rather than the mere presence of an ICD.

We received 6 comments from people who identified themselves as physicians or representatives of a physician group. Two of these commenters opposed allowing waivers for mariners with ICDs, arguing that the ICD itself presents an inordinate risk, and that the underlying condition would pose an inordinate risk. The Coast Guard disagrees. While acknowledging that there may be some cases where the ICD and the underlying condition pose an inordinate risk of sudden incapacitation, the Coast Guard has not found this to be true for all individuals. For

these reasons, the Coast Guard disagrees with imposing a blanket exclusion of waivers for all individuals with ICDs. This policy allows for an individualized assessment of the mariner. The criteria outlined in Enclosure (7) to NVIC 04-08 are designed to distinguish those individuals whose underlying conditions have substantially improved and no longer pose an unacceptable risk of sudden incapacitation. Individuals with ICDs who meet the stringent criteria outlined in this policy, are at low enough risk to warrant consideration for a medical waiver, and a blanket exlusion would unnecessarily put mariners out of work.

One of these commenters expressed the concern that an inappropriate ICD discharge might result in sudden incapacitation. The Coast Guard recognizes this concern, but found other comments to be more persuasive.

Specifically, cardiology experts commented on the low risk of inappropriate ICD discharge in this carefully selected population, and the ability to further mitigate such risk with selective device programming. Furthermore, these experts pointed out that with modern ICDs, the likelihood of an inappropriate ICD shock causing a sudden incapacitation is extremely small, and the benefits of having an ICD would outweigh any risk posed by the ICD in this setting.

Three of the other four physicians/physician groups agreed with establishing waiver criteria, but felt the proposed criteria were too restrictive (3 year exclusionary period, EF of 40%, 10 METs). The Coast Guard agrees in part. As noted above, we recognize that these criteria are strict, but necessary to demonstrate that individuals are at low enough risk to warrant consideration for a medical waiver. As discussed above, mariner credentials often enable individuals to work in safety-sensitive positions aboard vessels, which amplifies the risks and potential consequences of a condition requiring use of an ICD or anti-tachycardia device. Accordingly, the policy only grants waivers in those instances where the mariner's underlying condition has improved significantly such that it no longer poses an unacceptable risk of sudden incapacitation. Because the mariner's safety and public safety are at stake, the Coast Guard has chosen to maintain fairly stringent, objective criteria (to include requiring three years of clinical stability, recovery of the left ventricular ejection fraction and normal exercise capacity) in making the final decision on whether to grant a mariner's credential. As noted above, though, the Coast Guard concedes that the ability to attain 8 METs of exercise capacity, and an EF of 35%, along with meeting all

of the other criteria outlined in the policy, is sufficient to demonstrate low enough risk to warrant consideration for a medical waiver. Additionally, under exceptional circumstances, the policy allows for applicants who do not meet all of the criteria to be considered for a waiver if the risk of sudden incapacitation may be reduced.

# Seizure Policy

Generally, the final policy in Change-1 to NVIC 04-08 distinguishes between provoked and unprovoked seizures. A summary of the waiver criteria for both types of seizures is provided below.

Unprovoked seizures are those seizures not precipitated by an identifiable trigger. Mariners with a history of unprovoked seizure(s) may be considered for a waiver as follows:

- (1) Mariners with a history of epilepsy or seizure disorder may be considered for a waiver if the mariner has been seizure-free for a minimum of eight years (on or off anti-epileptic drugs (AEDs)); and
- (a) If all AEDs have been stopped, the mariner must have been seizure-free for a minimum of eight years since cessation of medication; or
- (b) If still using AEDs, the mariner must have been on a stable medication regimen for a minimum of two years.

- (2) Mariners with a single unprovoked seizure may be considered for a waiver if the mariner has been seizure-free for a minimum of four years, off AEDs; and
- (a) If all medication has been stopped, the mariner must have been seizure-free for a minimum of four years since cessation of medication; or
- (b) If still requiring treatment with AEDs, the mariner's condition will be considered under the criteria for epilepsy listed above in (1) (i.e., the mariner may be considered for a waiver after they have been seizure-free for a minimum of 8 years, and on a stable medication regimen for a minimum of two years).

Provoked seizures are those seizures precipitated by an identifiable trigger. (This does not include epileptic seizures or seizures brought on by lack of sleep, stress, or photo-stimulation. Seizures of this nature will be evaluated under the criteria for unprovoked seizures listed above). Mariners with provoked seizures can be divided into those with low risk of recurrence and those with a higher risk of recurrence (e.g., with a structural brain lesion).

(1) If a mariner is determined to be low-risk for seizure recurrence, does not require AEDs, and the precipitating factor is unlikely to recur, a waiver may be

considered when the mariner has been seizure-free and off medication for a minimum of one year.

- (2) Generally, mariners with one of the following precipitating factors will be considered low-risk for recurrence:
- (a) Lidocaine-induced seizure during a dental
  appointment;
- (b) Concussive seizure, loss of consciousness ≤30 minutes with no penetrating injury;
  - (c) Seizure due to syncope not likely to recur;
- (d) Seizure from an acute metabolic derangement not likely to recur;
  - (e) Severe dehydration;
  - (f) Hyperthermia; or
  - (g) Drug reaction or withdrawal.
- (3) If a mariner is determined to be at higher risk for seizure recurrence, a waiver may be considered if the mariner has been seizure-free for a minimum of eight years (on or off AEDs); and
- (a) If all medication has been stopped, the mariner must have been seizure-free for a minimum of eight years since cessation of medication; or
- (b) If still using AEDs, the mariner must have been on a stable medication regimen for a minimum of two years.

- (4) Generally, mariners with a history of provoked seizures caused by a structural brain lesion (e.g., tumor, trauma, or infection) characterized by one of the following precipitating factors will be considered at higher risk for recurrence:
- (a) Head injury with loss of consciousness or amnesia≥30 minutes or penetrating head injury;
- (b) Intracerebral hemorrhage of any etiology, including stroke and trauma;
- (c) Brain infection, such as encephalitis, meningitis, abscess, or cysticercosis;
  - (d) Stroke;
  - (e) Intracranial hemorrhage;
- (f) Post-operative brain surgery with significant brain hemorrhage; or
  - (q) Brain tumor.
- (5) Under exceptional circumstances in which a mariner has had provoked seizures due to a benign brain lesion that has subsequently been removed, such individuals may be considered for a waiver once they have been seizure-free for a minimum of four years, provided that objective evidence supports extremely low risk of seizure recurrence. Public Comments on Seizure Policy

On March 25, 2013 we published a notice in the <u>Federal</u>

<u>Register</u> requesting public comments on proposed policy

regarding waivers for mariners with seizure disorders (78

FR 17917). We received 7 comments on the proposed policy

for granting waivers for mariners with seizure disorders.

The majority of commenters supported the proposed policy.

One commenter agreed with the proposed policy, noting that the criteria are strict, but appropriate when considered in light of the risks associated with a mariner having a seizure while in a safety-sensitive position aboard a ship.

Another commenter questioned whether it was appropriate for the Coast Guard to consider the guidelines and recommendations of the Federal Motor Carrier Safety Administration (FMCSA) Medical Review Board (MRB) and FMCSA's Medical Expert Panel regarding seizure disorders in automobile drivers when developing similar Coast Guard policy for mariners (see 78 FR 17918).. The commenter suggested that mariners may need to undergo stricter evaluations than automobile drivers, such as evaluation by immersion in sea simulation and video electronystagmography to study their vestibular systems. The Coast Guard agrees that there may be special situations where certain mariners may require more extensive evaluation. NVIC 04-08 reflects

that approach by giving the Coast Guard discretion to apply stricter standards on a case-by-case basis as needed. The Coast Guard disagrees that sea simulation and electronystagmography testing should be a blanket requirement for all mariners with seizure disorders.

Neither the commenter nor the relevant medical literature provided acompelling rationale to justify such comprehensive vestibular testing for every mariner with a seizure disorder. Accordingly, the Coast Guard will determine whether an individual mariner requires extensive vestibular evaluation on a case-by-case basis, in consultation with the mariner's treating neurologist.

One commenter generally disagreed with the proposed policy, arguing that it was too strict. This commenter felt that it should be sufficient for mariners to demonstrate that their condition is under control and they are under the care of a doctor. The Coast Guard disagrees. As discussed above, mariner credentials often enable individuals to work in safety-sensitive positions aboard vessels, which amplifies the risks and potential consequences of a seizure disorder. Accordingly, the Coast Guard has determined that a mariner's self-evaluation, or even the evaluation of a physician, is not sufficient evidence that a seizure disorder poses no inordinate risk.

While the Coast Guard gives the treating physician's evaluation great weight, it is not the sole factor to consider. Because the mariner's safety and public safety are at stake, the Coast Guard has determined it must also consider the objective criteria described above in making the final decision of whether to grant a mariner's credential.

Notably, the Epilepsy Foundation provided comments in support of the proposed policy. The Epilepsy Foundation identifies itself as the leading voluntary health agency working on behalf of people with epilepsy. The Epilepsy Foundation applauded the Coast Guard's efforts to develop a policy that recognizes the potential for mariners with seizure disorders to work, while allowing for a case-bycase evaluation of the applicant's fitness. The Epilepsy Foundation also noted that epilepsy is a highly variable disorder, with varying levels of seizure control in different individuals. The Epilepsy Foundation pointed out that this variability makes it difficult to generalize about safety concerns and makes it inappropriate to enact blanket exclusionary rules and qualification standards that bar individuals with epilepsy. The Coast Guard agrees. Our policy has always included an individualized evaluation of the mariner's condition to determine fitness.

developed the criteria outlined in this policy to provide a framework within which to make these evaluations and to provide a margin of safety for individuals with seizure disorders who are seeking to work in a safety-sensitive position.

We also received 3 comments from individuals who self-identified as physicians or representatives of physician groups. All agreed with the decision to grant waivers for individuals with seizure disorders. One physician argued that the criteria are too restrictive because the required seizure-free time intervals are too long. The Coast Guard agrees that the criteria are stringent, but believes they are necessary to ensure the mariner's safety and public safety.

One of the physicians contended that the criteria are not strict enough. This physician expressed support for a 10-year seizure free time period for seizures, similar to that recommended for commercial drivers by the FMCSA's MRB. The Coast Guard disagrees. The aim of this policy is to distinguish those individuals who are no longer at inordinate risk of seizure recurrence. As part of the background research for determining a reasonable seizure-free time interval, the Coast Guard considered the recommendations of the FMCSA's MRB, which uses a 10-year

seizure-free requirement, as well as the recommendations of the FMCSA's 2007 Neurology Medical Expert Panel (MEP). 2007 Neurology MEP asserted that individuals with certain types of seizures would be at low risk of seizure recurrence after 8 years or 4 years seizure-free. Coast Guard found the recommendations of the 2007 MEP, which were based upon contemporary medical literature and research, to be more persuasive than the suggestion advocated by this commenter or the position of the FMCSA MRB. The 4-year and 8-year seizure-free time intervals allow sufficient time for individuals to demonstrate clinical stability and to distinguish those who are at lowest risk of seizure recurrence. Additionally, the Coast Guard notes that the FMCSA has recently announced its decision to utilize the recommendations of its 2007 MEP as the basis for evaluating commercial drivers with epilepsy. Those recommendations are similar to the criteria outlined in the Coast Guard's policy.

The third physician group, the American Epilepsy

Society (AES), agreed with the policy as proposed. The AES

acknowledged that the criteria strict, but agreed that such

criteria are necessary to address public safety concerns.

The Coast Guard agrees and will continue to assess whether

this policy strikes the proper balance between public

safety and an individual's interest in holding a merchant mariner credential.

The AES, the Epilepsy Foundation, and one selfidentified physician also provided responses to the seven questions that the Coast Guard posed in the March 25, 2013 Federal Register notice as follows:

- evidence that chronic use of anti-epileptic drugs (AEDs) impairs judgment and reaction time, both AES and the Epilepsy Foundation stated that AEDs used in appropriate dosages do not affect these functions or result in cumulative impairment. The other commenter noted that all AEDs have the potential to impair judgment, mood and motor skills, but recommended that this be considered on an individual basis, instead of drawing a blanket conclusion. The Coast Guard agrees. The policy does not impose a blanket disqualification for use of AEDs; instead it allows the Coast Guard to consider the treating neurologist's assessment of medication impairment when making a final determination.
- (2) All three of these commenters stated that there is no evidence that individuals who have been seizure-free and off AEDs for a period of time have a lower likelihood of seizure recurrence than individuals who have been

apparently seizure-free and on stable AED dosing. The Coast Guard agrees. The policy allows for those individuals with seizure disorders who require treatment with AEDS to be considered for waivers, similar to those who do not require treatment with AEDs.

- (3) On the question of risk of seizure recurrence as a function of time since the last seizure among individuals on AEDs who are apparently seizure-free, AES and the Epilepsy Foundation advised that the risk of recurrent seizures decreases with time seizure-free, on or off AED The other commenter opined that the risk of medications. seizure recurrence in this setting was uncertain and dependent upon too many variables. The Coast Guard agrees with both answers. Because the risk of seizure recurrence decreases with time seizure-free, the policy requires a minimum seizure-free time interval before an affected individual can be considered for a waiver. Additionally, in acknowledgement of the many variables that might affect likelihood of seizure recurrence in a particular individual, the policy allows for an individualized assessment and considers the risk evaluation of the treating neurologist.
- (4) On the question of the likelihood of seizure recurrence as a function of time in individuals who are

seizure-free following removal of a benign brain tumor, none of the commenters gave a specific answer. AES and the Epilepsy Foundation advised, however, that such a situation was already accounted for in the policy. The other commenter asserted that the answer was too variable to generalize. The Coast Guard agrees. The policy specifies a minimum seizure-free time interval for such individuals, but also allows for an individualized assessment.

(5)-(6) Questions five and six asked about the need and appropriateness of applying operational limitations and/or restrictions for mariners with seizure disorders. Both AES and the Epilepsy Foundation pointed out that the seizure-free time requirements outlined in the policy are conservative enough that if exceeded, there should be no need to differentiate between roles. However, they did recommend that less restrictive criteria be applied to individuals who do not operate dangerous machinery, work over 10 feet above ground, pilot a vessel, or stand watch alone. For these individuals, they recommended consideration for specific jobs if they have been seizure free for one year and on stable medications for one year. The other commenter advised that use of operational restrictions and limitations may be reasonable depending on the individual's job function and circumstances. The Coast

Guard agrees and will consider applying operational limitations and/or restrictions on a case-by-case basis, when appropriate.

(7) Question seven asked if there are individuals with seizure disorders due to a structural brain lesion that are at low-risk for seizure recurrence. Both AES and the Epilepsy foundation noted that individuals with structural brain lesions are at higher risk, as reflected in the longer restriction times outlined in the policy. The other commenter noted that the answer would depend on the definition of structural brain lesion. The Coast Guard agrees. The policy outlines a minimum seizure-free time interval for such cases, while allowing for an individualized assessment and consideration of exceptional circumstances.

# III. Authority

This notice is issued under the authority of 5 U.S.C. 552(a), 46 U.S.C 7101 et seq., 46 CFR 10.215, and Department of Homeland Security Delegation No. 0710.1.

Dated: August 28, 2013.

J. C. Burton,
Captain, U.S. Coast Guard,
Director of Inspections & Compliance.

[FR Doc. 2013-23114 Filed 09/20/2013 at 8:45 am; Publication Date: 09/23/2013]